

IN THE UNITED STATES DISTRICT COURT FOR THE
WESTERN DISTRICT OF MISSOURI
ST. JOSEPH DIVISION

ROBERT KIESER,

Plaintiff,

v.

C.R. BARD, INC., et al.,

Defendants.

Case No. 5:20-cv-06045-NKL

ORDER

Before the Court is Defendant C.R. Bard, Inc., and Bard Peripheral Vascular, Inc.’s (collectively, “Bard”) Motion to Strike the Expert Report of J. Lawrence Stevens, RAC. Doc. 50. Plaintiff Robert Kieser has disclosed Steven’s expert report, wherein Stevens relies on his insight into the FDA regulatory process to offer opinions on whether Bard acted as a reasonably prudent manufacturer of medical device when marketing its IVC filters. Bard moves to strike Kieser’s testimony as contained in his expert report because it consists entirely of non-case specific opinions, the time for offering such general opinions has closed, and that its untimely admission would cause unfair prejudice. For the reasons stated below, Bard’s Motion is granted in part and denied in part.

1. Background

On April 9, 2018, this case was consolidated into the multidistrict litigation proceeding *In re Bard IVC Filters Product Liability Litigation*, 15-md-02641-PHX, before the Honorable David G. Campbell in the United States District Court for the District of Arizona for the purpose of

completing general discovery. Doc. 2. On March 5, 2020, it was remanded to this Court with the following direction:

“Because all general fact and expert discovery has been completed in this MDL, the courts receiving these cases need not be concerned with facilitating general expert, corporate, and third-party discovery. This observation is not meant to restrict the power of receiving courts for good cause or in the interest of justice to address issues that may be unique and relevant in a remanded or transferred case.”

Doc. 3, at 31.

On December 21, 2020, Kieser filed his Fed. R. Civ. P. 26 Expert Designations, wherein he designated Stevens as an expert on the topics of “FDA”, “Regulatory”, and “Corporations.” Doc. 39, at 2. Bard deposed Stevens on February 16, 2021. Doc. 73.

Stevens in his report opines on whether Bard acted as a reasonably prudent manufacturer in marketing its G2 filter after reviewing its internal documents and depositions of its employees. Doc. 51-1 (Stevens Report). He uses his experience in the FDA and his resulting expertise to opine on Bard’s internal deliberations and the reasonableness of their actions. Specifically, he opines that Bard did not adequately warn of the increased risks associated with its new filters, *id.*, at 64, and that a reasonably prudent manufacturer would not have marketed the filters in question to doctors after becoming aware of reports of elevated caudal migration. *Id.*, at 69. Stevens only glancingly references Kieser of his report and does not meaningfully connect the specifics of Kieser’s case to his testimony, which is broadly concerned with Bard’s decisionmaking in bringing its filters to market and its ongoing regulatory obligations. Stevens also offers some opinions that are duplicative of those offered by other general experts, including Dr. Kinney and Dr. Hurst, when he discusses reasonable physician expectations. *Id.* at 43, *See* Doc. 51-6, at 9-10; (Kinney Report); Doc. 51-5, at 9 (Hurst Report).

Bard contends, and Kieser essentially concedes,¹ that Stevens' opinions are most aptly characterized as general opinions. Kieser Br. at 16 ("Larry Steven's report would have little to do specifically with Plaintiff Robert Kieser himself other than opining that if Bard, as a manufacturer of a medical device, had not breached its duty to properly warn and/or recall the product in a timely manner the filter would not have been implanted and/or caused harm to plaintiff.)".

2. Legal Standard

District courts have broad discretion in ruling on the admission of expert testimony. *Clark v. Hedrick, M.D.*, 150 F.3d 912, 915 (8th Cir. 1998); *Jackson v. Allstate Ins. Co.*, 785 F.3d 1193 (8th Cir. 2015). Under Fed. R. Evid. 403, expert testimony may be excluded if its probative value is substantially outweighed by unfair prejudice, the likelihood of confusion, undue delay, or cumulativeness. In addition, a federal court "to which an MDL case is transferred or remanded" may revisit the MDL court's decision only in exceptional circumstances so as to prevent the possibility of inconsistent pretrial rulings. *Clinton v. Mentor Worldwide LLC*, 2016 WL 7491861, at *8 (E.D. Mo. Dec. 30, 2016) (citing *Deutsch v. Novartis Pharm. Corp.*, 768 F. Supp. 2d 420, 429 (E.D.N.Y. 2011)).

3. Discussion

¹ Kieser summarily asserts that the Stevens Report contains two case-specific opinions: (1) "The G2 implanted in Mr. Leus' [sic] body was not safe for its intended purpose because Bard failed to provide adequate warnings; and (2) As of April, 2006 the G2 was an adulterated device in accordance with federal regulations requiring removal from the market. Obviously, a jury could infer that if the product was removed from the market prior to the implant date it could not have caused harm to Plaintiff." Kieser Br. at 15. Neither of these opinions are case-specific. The first opinion could apply equally to every person implanted with the G2 filter, a truth aptly demonstrated by the fact that Kieser's counsel in this sentence inadvertently substituted Kieser's name with that of another *Bard* plaintiff in this district. See *George Leus v. C.R. Bard, Inc.*, 4:13-cv-00585-GAF. The second opinion, similarly, contains no opinion specific to Kieser's particular injury or circumstance.

Bard argues the Stevens Report should be struck because (1) it lacks case-specific opinions; (2) its admission is an attempt to supplement general discovery, which the MDL Court has declared closed; and (3) its admission would unfairly prejudice Bard if admitted. Kieser has essentially conceded that the Stevens report offers general opinions. As such, the Court will focus on whether the admission of Stevens' general opinions would run afoul of the MDL Court's Transfer Order or unfairly prejudice Bard.

a. Violation of MDL Transfer Order

To review, the MDL Court's Transfer Order stated that "courts receiving these cases need not be concerned with facilitating general discovery" because "all general fact and expert discovery has now been completed[.]" Doc. 3, at 9. Bard argues that the Kieser's late attempt to include Stevens' testimony is a blatant violation of the MDL Court's direction that general discovery had been completed as of August 20, 2019.

Kieser responds not by disputing Bard's characterization of Stevens' testimony but by elaborating on the circumstances that led it to seek its admission post-remand. Those circumstances are as follows: In the MDL, plaintiffs designated two different experts who, after reviewing Bard internal communications, opined as to its duty as a medical device manufacturer, specifically in relation to the FDA regulatory process. Those experts were Dr. David Kessler, the former commissioner of the FDA, and Dr. Susan Parisian, a doctor well-versed in the FDA's regulatory process for medical devices. Bard's alleged failure to meet the standard of care required of a medical device manufacturer is an element in three of Kieser's claims: Strict Liability Failure to Warn (Count 2); Negligent Failure to Recall; (Count 6); and Negligent Failure to Warn (Count 7). Doc. 1, at 3.

Kessler and Parisian submitted expert reports which were adjudicated in the MDL proceeding. MDL D.E. 9433 (Kessler and Parisian *Daubert* Order, granting in part and denying in part Bard’s motions to exclude).² They were also deposed in the MDL proceeding. MDL D.E. 7308-3 (Parisian Depo.), 7309-2 (Kessler Depo.). However, neither were called as witnesses at any bellwether trials and have since become unavailable for preservation depositions or to testify at this trial—Kessler by reason of appointment to a senior position in the Biden transition and administration, and Parisian by reason of a serious illness. Bard does not dispute the unexpected unavailability of Kessler or Parisian.

Kieser claims these circumstances leave him in the lurch. At trial, he would be forced to rely on stitched-together deposition transcripts from Kessler and Parisian to make his case regarding Bard’s manufacturing duty and its FDA dealings. He claims that “Even if Plaintiff is by some remote chance able to make a submissible case through disjointed deposition transcripts it will be one the jury would really never understand.” Kieser Br. at 13-14. To save these claims, Kieser has designated Stevens as a “replacement expert required under these unique circumstances such as would be created if an expert had died unexpectedly prior to trial and no preservation deposition had been taken because the death was unexpected.” *Id.* at 14-15. Kieser admits that “Mr. Stevens was retained for no other reason than the fact that Dr. Kessler and Dr. Parisian, the MDL FDA experts, are unavailable and no preservation depositions exist for plaintiff to properly advance his claims at trial.” *Id.* at 16.

² The MDL Court excluded Kessler’s testimony regarding Bard’s intent, motive, or ethics, along with the specifics of its IVC filter designs, but allowed him to opine on FDA regulatory issues relating to Bard filters, including whether the FDA would have approved a particular device if certain information about the device had been disclosed. MDL D.E. 9433, at 17-18. The MDL Court excluded Parisian’s testimony regarding Bard’s intent, motive, or ethics, or matters relating to physician expectations, but allowed her to opine on FDA practices and Bard’s participation in the FDA regulatory process. *Id.* at 8-9.

Bard’s argument that Stevens’ testimony must be struck because it consists entirely of general opinions depends on the proposition that the MDL Court’s Transfer Order categorically prevents this Court from permitting further general discovery. It cites two cases in support of that proposition—*Harris v. Wyeth, Inc.*, 2012 WL 2317338, at *1 (S.D.N.Y. June 15, 2012), and *Kelly v. Ethicon, Inc.*, 2020 WL 5949225, at *6, 8 (N.D. Iowa Oct. 7, 2020). In *Harris*, the district court wrote in dicta that the key purpose of consolidating general discovery into an MDL would be frustrated if courts were allowed to facilitate further general discovery post-remand and that allowing a party to conduct further generic discovery “would render the more than seven years spent in the MDL Court largely for naught.” *Harris*, 2012 WL, at *1. In *Kelly*, the district court agreed with the proposition that “As a general matter, the transferer court is bound, upon remand, by the orders entered by the transferee court during the coordinated or consolidated pretrial proceedings. Those decisions are considered law of the case.” *Kelly*, 2020 WL, at 3 (quoting *In re Welding Fume Prod. Lab. Litig.*, 2010 WL 7699345, at *2 (N.D. Ohio June 4, 2010)). However, it also stated that although as a general rule the district judge on remand must defer to the decisions of the MDL Court, the district judge can vacate or modify the rulings of the MDL court when there has been a significant change in circumstances. *Id.* (quoting *Manual for Complex Litigation* § 20.133, at 226 (4th ed. 2004)).

Neither of these cases support Bard’s theory that this Court is categorically bound by the MDL Court’s observation that general discovery has been completed. Rather, they confirm that although this Court should defer to the MDL Court as a general matter in the interest of efficiency, consistency, and comity, it is permitted to reopen general discovery if there has been a significant change in circumstance post-remand. Even if this Court were bound by the MDL Court’s Transfer Order, the Order by its own terms did not “conclusively” close general discovery as Bard claims.

Bard Br. at 4. The MDL Court, after observing that district courts need not be concerned with further general discovery, stated “This observation is not meant to restrict the power of receiving courts for good cause or in the interest of justice to address issues that may be unique and relevant in a remanded or transferred case.” Doc. 3, at 31. This language explicitly allows district courts to permit further general discovery “to address issues that may be unique and relevant[.]” *See Robinson v. C.R. Bard, Inc.*, 2020 WL 888300, at *2 (E.D. Mo. Feb. 24, 2020) (finding the pronouncements in the same Transfer Order did not “mandate against reopening general discovery” and permitted a limited reopening of discovery that was “proportional to the needs of the case and in the interests of justice.”).

The unexpected unavailability of both Kessler and Parisian constitutes a significant change in circumstance justifying the limited extension of general discovery so as to allow an expert to present to the jury in a comprehensible fashion the opinions already offered, adjudicated, and admitted in the MDL proceedings. Although Kessler and Parisian were deposed in the MDL proceeding, their depositions were taken for purposes of *Daubert* challenges, not to develop cogent testimony regarding Bard’s manufacturing duty meant for a jury. Although Kieser’s counsel could attempt to stitch together excerpts from these old deposition transcripts to present his argument, the Court accepts his representation that proceeding in this manner would be of marginal use to the jury. In light of these significant changed circumstances, the Court believes that a limited reopening of general discovery solely to permit Kieser to offer those opinions of Steven’s already offered by Parisian and Kessler is proportional to the needs of the case and in the interest of justice. Consequently, it will not strike Stevens’ testimony on this basis.

To ensure the MDL Court remains the forum where general opinions were offered and ruled on in the first instance, Stevens will only be able to offer testimony that is consistent with

Kessler's and Parisian's testimony and admitted by the MDL Court in its relevant *Daubert* Order. MDL D.E. 9433. In addition, Stevens will not be allowed to opine on topics covered by other general opinion experts, such as Dr. Hurst or Dr. Kinney, as such testimony would be cumulative, in violation of the MDL Transfer Order, and not justified by any change in circumstance.

b. Prejudice

Bard argues it will be severely prejudiced if Kieser is allowed to present Stevens' testimony as contained in his expert report because it would be forced to "relitigate previously raised issues in the MDL Court" and would "face the additional burden and expense . . . of having to refute this highly prejudicial and cumulative evidence." Bard Br. at 11. In addition, it would need to "designate additional experts so as to rebut new general opinions offered by Plaintiff[.]". *Id.*

Bard is under no obligation to relitigate previously raised issues or designate additional experts to rebut Stevens' testimony. To the extent Bard has stated in its briefing that Stevens' testimony is duplicative of testimony already offered and adjudicated before the MDL Court, the burden and expense of briefing these same issues again should be negligible. Furthermore, Bard's contention that it will need to designate additional experts to rebut Stevens' new general opinions is not persuasive in light of the fact that Stevens will not be allowed to present any new general opinions. As such, whatever rebuttal testimony Bard has already marshalled in response to Kessler and Parisian should apply with equal force to Stevens' testimony. Finally, the Court notes that Bard has already deposed Stevens on the opinions contained in his expert report. Doc. 73. On this record, the probative value of Stevens' limited testimony outweighs Bard's prejudice. Consequently, the Court will not strike Stevens' testimony on the basis of unfair prejudice.

Conclusion

For the reasons explained above, Bard's Motion to Strike is granted in part and denied in part. It is granted to the extent that Stevens' testimony contains opinions that (1) were not already offered by Kessler or Parisian and admitted in the MDL proceeding or (2) were offered by another general expert in the MDL proceeding. The balance of the Motion is denied.

Bard requests that to the extent its Motion is denied that it be allowed 14 days from the date of this order to serve rebuttal expert reports on Kieser. This request is granted, and Bard has until 14 days from the date of this order to serve any rebuttal expert reports on Kieser.

IT IS SO ORDERED.

s/ Nanette K. Laughrey
NANETTE K. LAUGHREY
United States District Judge

Dated: March 9, 2021
Jefferson City, Missouri